REMARKS

The Examiner's Office Action mailed April 1, 2010, which rejected all pending claims, has been reviewed. Reconsideration in view of the foregoing amendments and remarks is respectfully requested. Moreover, Applicants have reviewed the Office Action of April 1, 2010, and submit that the above Amendments and the following Remarks are responsive to all points raised therein. Applicants believe that currently pending claims 1 and 4-5 are now in form for allowance.

Status of Claims

Claims 1 and 4-5 are pending in the application. Claims 3, 6, and 7 have been canceled. Claim 1 has been amended to incorporate the limitation of claim 3. No new matter has been added.

Claim Objection

Claim 1 has been amended and no longer includes the informality noted by the Examiner. Applicants request the withdrawal of the objection to claim 1.

Rejection of Claims 1, and 3-7 under 35 USC 112, second paragraph

Reconsideration is requested of the rejection of claims 1, and 3-7 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claim 1 and submit that the amendment is sufficient to overcome the rejection to claim 1. Applicants request the withdrawal of the rejection to claim 1.

Rejection of Claims 1, and 3-7 under 35 USC 103(a)

Reconsideration is requested of the rejection of claims 1, and 3-7 under §103(a) as being unpatentable over Schulz et al (US 2003/0045544) in view of

Vetter et al. (US 5808076) and Himmler et al (Abstracts of the interscience conference on Antimicrobial Agents and Chemotherapy (2002)).

Schultz et al. teach the use of chemotherapeutic agents, such as described by formula (I), for topical and local treatment of diseases caused by bacteria in humans and animals. Schultz focuses the administration of the agents is topically or locally (see paragraphs 37-77). As the Examiner correctly stated, Schultz does not disclose the systemic treatment of bacterial infections or the oral cavity diseases as recited by the claims. It only teaches topical or local application.

Vetter et al. teach quinolone embonates, specific formulations of quinolones that are administered orally. Vetter et al., however, does not teach pradofloxacin and it does not disclose the systemic treatment of bacterial infections of the oral cavity, unlike as suggested by the Examiner.

Himmler et al. teach the synthesis and in vitro activity of pradofloxacin. The in vitro activity shown is with regards to *E. Coli*, *S. aureus* and *S. intermedius*.

The Examiner states that it would have been prima facie obvious for one skilled in the art at the time of the invention to use pradofloxacin to systemically treat bacterial infections of the oral cavity in humans or animals in need thereof. The Examiner comes to this conclusion by stating that Schultz et al. teach fluoroquinolones for the local or topical treatment of oral cavity infections, Vetter et al. teach systemic activity of fluoroquinolones against various bacteria, and therefore someone skilled in the art would combine the teachings of Shultz et al. and Vetter et al. to develop a method treating bacterial infections of the oral cavity by systemic administration of pradofloxacin and other fluoroquinolones. The Examiner then states that Himmler provides additional motivation to use pradofloxacin as it showed the lowest MIC in comparison to other fluoroquinolones in inhibiting *E. Coli*, *S. aureus* and *S. intermedius*.

Applicants respectfully disagree with the Examiner. First, Himmler teaches away from the invention, or in the alternative should not be combined with the Schulz and Vetter reference, as *E. Coli*, *S. aureus* and *S. intermedius*,

although bacteria, are not strains of bacteria of the oral cavity. Someone skilled in the art trying to develop a method of treating a bacterial infection of the oral cavity would not look to Himmler to compare the MIC of different fluoroquinolones against strains of bacteria that are not of the oral cavity. At the time of the invention it was known that many quinolone antibiotics were not effective against oral bacteria. As such Himmler, would not be used by someone skilled in the art trying to develop a method of systemically treating a bacterial infection of the oral cavity. Second, as stated above, Vetter et al. do not teach pradofloxacin and as the Examiner correctly stated, Schultz does not disclose the systemic treatment of bacterial infections or the oral cavity diseases as recited by the claims. It only teaches topical or local application. As such, even if combined, which applicants submit someone skilled in the art would not do, the references would not teach the present invention.

In addition, Applicants submit herewith a declaration by Dr. Bernd Stephan and a study conducted wherein the minimal inhibitory concentration (MIC) for pradofloxacin and des-cyanopradofloxacin of 31 anaerobic bacterial pathogens isolated from cases of canine periodontal disease were compared. This study and data is submitted to show that not all fluoroquinolones have similar activity against bacterial that are relevant in the treatment of oral infections. The data shows that pradofloxacin is clearly more effective against these anaerobic bacteria than des-cyano-pradofloxacin, even though they are both fluoroquinolones.

In addition, infections of the oral cavity are also unique in other aspects. For example, the systemically administered antibiotic needs to be present in the tissues of the oral cavity in effective concentrations. If an antibiotic is effective in other parts of the body that does not necessarily mean that concentrations in the oral cavity are also sufficiently high. There are many antibiotics which are generally effective but are not sufficiently effective in oral infections.

If all these difficulties are taken into account it will be understood that there are only few antibiotics which are known to be particularly suitable for the systemic treatment of infections of the oral cavity. One well established antibiotic

which is particularly suitable for this purpose is metronidazol; the data in Example 1 show that the activity of pradofloxacin against tested anaerobic bacteria is even better than the activity of metronidazol. This is another unexpected result for a quinolone.

As such Applicants submit claims 1, 4, and 5 are patentable over Schultz et al. in view of Vetter et al. and Himmler et al.

Conclusion

In view of the above, Applicants respectfully submit that the pending claims are novel and not obvious over the cited references and request withdrawal of all rejections and allowance of the claims.

The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment in connection with this amendment to Deposit Account No. 50-4260.

Respectfully submitted,

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